SEP 1 8 2000

Baxter

K002679

510(K) SUMMARY

Submitted by:

Jennifer M. Paine
Associate II, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Name/Classification of Device
Infusion Pump/ Class II, 80FRN – 21 CFR 880.5725

Trade Names:
6060™ Multi-Therapy Infusion Pump
6060™ Epidural Pump

Predicate Device:
Sabratek® 6060 Homerun™ pump, #K941984 cleared on 07/19/94 and acquired by Baxter Healthcare Corporation on January 21, 2000.

Statement of Intended Use:

The 6060™ Multi-Therapy pump is intended for volumetric delivery of fluids in enteral, epidural, subcutaneous, arterial, intracavity, and intravenous applications. The 6060™ E pump is marketed as a pump specifically identified for epidural delivery.

Device Description:

Baxter's 6060™ pumps are compact, lightweight, microcomputer-controlled pumps that use rotary peristaltic pumping technology. The modified devices will differ only slightly from those currently marketed. Baxter Healthcare proposes to modify the predicate device to upgrade software and pump memory. The modifications described in this submission are: (1) additional software feature (Circadian programming mode), and (2) conversion from EPROM to "flash" memory chips.

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Summary of Technological Characteristics of New Device to Predicate Devices

The technological features of the modified 6060™ Multi-Therapy pumps do not differ significantly from the currently marketed 6060™ pumps. The subject and predicate devices are similar in design, material composition, components, labeling, and manufacturing processes. The subject and predicate devices are identical in intended use. There are technological differences between the subject and predicate devices, but these differences do not raise new issues of safety and effectiveness.

Discussion of Non Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Ms. Jennifer M. Paine
Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K002679
Trade Name: 6060 Multi-Therapy Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 25, 2000
Received: August 28, 2000

Dear Ms. Paine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: 6060™ Multi-Therapy Infusion Pump

Indications For Use:

The 6060™ Multi-Therapy pump is intended for volumetric delivery of fluids in enteral, epidural, subcutaneous, arterial, and intravenous applications. The 6060™ E pump is marketed as a pump specifically identified for epidural delivery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucuzzella
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002679

For Special 510(k) K002679 9/13/00